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SUBMITTED VIA ELECTRONIC MAIL

FSIS Docket Clerk
Docket No. 95-051P
300 12th Street SW
Washington, DC 20250-3700

FDA Division of Dockets Management
Docket No. 1995N-0294
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA and FSIS Proposed General Principles for Food Standards and Planned Reliance on Petitions Submitted by External Groups to Establish, Revise, or Eliminate a Food Standard.

To FSIS and FDA:

This letter is intended to offer comments on the proposed rules published by each of your respective agencies[1] in the Federal Register to establish a set of general principles for food standards. *See* 70 Fed. Reg. 97, 29214-29235 (May 20, 2005). The comments are offered on behalf of our law firm (www.marlerclark.com), and in our roles as food safety advocates (www.outbreakinc.com and http://www.fsis-pfge.org). Because we oppose the outsourcing to external parties of efforts to modernize food standards to protect the public and promote honesty and fair-dealing, we also oppose the adoption of the proposed rule. If the proposed rule is adopted, however, the petition process the Agency intends to rely on should be made as transparent as possible, and petitioners should be required to make proposals available for public comment prior to, or as part of, the submission process. It should also be made clear by the agency that, while labeling standards may preempt state law regulation to the contrary regarding labels, such preemption is not intended to go any further than that. Specifically, state tort liability is not intended to be preempted, and that a person injured by a defective product will remain entitled to recover damages from the

[1] For ease of reference, the FDA and FSIS will be referred to collectively as the "Agency."

manufacturer of the product. A federal agency should not bar states from using damages as a means of ensuring its citizens are compensated in the case of product-related injury.

OUR SPECIFIC COMMENTS

There is an important distinction—historically, legally, and practically—between the rules and policies promulgated pursuant to agency authority to protect the public from "adulterated" food and the rules and policies promulgated pursuant to agency authority to protect the public from "misbranded" food. *Compare* 21 U.S.C. § 601(m) ("adulterated") *with* 21 U.S.C. § 601(n) ("misbranded"). As we understand it, the present proposed rules deal solely with "misbranded" food, and agency authority to regulate "labeling" of food products under its jurisdiction. For this reason, the Agency states it has a "responsibility for ensuring that food labels are truthful and not misleading," and "[f]ood standards are used to ensure that products sold under particular names have the characteristics expected by consumers." [29227] This is all well and good. But the Agency does not state how its primary, if not exclusive, reliance on external parties to petition for changes to existing food standards will sufficiently protect the interests of consumers and the public.

The Agency states that "all food standards, *including those for which [it] receives no petitions*, will be modernized or eliminated." [29225, italics ours] It further states, "in the event we do not receive a petition...we may, when appropriate, propose to establish, revise or remove a standard on our own initiative." *Id.* It does not state, however, by what means the Agency will exercise this initiative. The Agency admits that the proposed rule is driven, in large part, by the recognition that "limited resources and competing priorities make it unlikely that the agencies could complete a comprehensive review of all food standards on their own initiative in a timely manner." [29225] But what evidence is there that these same "limited resources and competing priorities" will not prevent the Agency from exercising the initiative necessary to ensure all food standards are either modernized or eliminated? Indeed, when the Agency states that it wants to make "clear to interested parties that they should submit petitions if they desire changes in standards, rather than wait for us to act on our own initiative," it sounds like it is stating that no change will be made except in response to a petition. Otherwise, why make such a statement?

Of course, exclusive reliance on petitions to effect change is not necessarily a bad thing if the proposed process were to, in fact, result in the hoped-for modernization. But the Agency estimates that no more petitions will be received after the adoption of the proposed rule than before. It states:

> We received 10 petitions from 200 through 2004, or approximately three petitions per year. The proposed rule might either increase or decrease the number of petitions. However, we do no have sufficient information to estimate a change in the expected number of petitions. Therefore, we assume that we will continue to receive three petitions per year.

[29232, emphasis added]

The primary rationale for the proposed rule—a comprehensive review of all food standards in a timely manner—is undercut, if not entirely refuted, by the Agency's own estimate of how many petitions it is likely to receive. Based on the Agency estimates, the review process will go forward at precisely at the same pace as at present, and result in no substantial savings of Agency resources. Consequently, as the Agency is forced to acknowledge, the proposed rule:

> transfers some of the costs that we currently bear to private individuals and groups, thereby allowing us to reallocate our resources to issues that may have greater public health significance, while still allowing us to address standards reform in a timely fashion. However, this public health benefit is probably small because we have been unable to devote significant resources to standards reform to-date.

[29227, emphasis added] Given that the Agency is not expecting additional resources as a result of the proposed rule, and no increase in the number of petitions received, then it is not clear what the proposed rule accomplishes, except for shifting the blame for the slow pace of food standard modernization to external parties.

The Agency concedes that no one is going to invest the time necessary in making a petition unless the resulting change in the food standards is likely to be profitable. "For example, external parties that work for for-profit entities will presumably submit petitions only if the changes request will increase their profits by more than the cost of preparing the petitions." [29277] In light of this presumption, the Agency states that it will still be able to identify "inappropriate recommendations during the petition review process," but it does not say how that this will occur, or even how that it occurs now. This additional information should be provided to the public before the adoption of the proposed rule. If the present petition process is working, those being asked to comment on the proposed rule need to know that. If, on the other hand, it is not working—which certainly seems to be the case—then those commenting need to know that as well.

Regarding transparency, the proposed rule encourages the active seeking of public input, but does not require it. One must reasonably assume that a person or company will not invest the time and effort necessary to prepare a petition without doing so with the goal of having it granted, or otherwise result in agency action favorable to the petitioner. It is therefore not reasonable to assume that a petitioner will seek input contrary to the case being made. As such, the agencies should either require that a petitioner demonstrate that it has sought input, or the Agency should put in place some process reasonably likely to generate such input. It is not enough to observe, as the Agency does, that the public will have an opportunity to provide input after the petition review process is completed and a proposed rule is published. The petition process needs to be transparent and allow for public input prior to start of the rulemaking process. The Agency's thinking is likely to be too fixed at that point for comments to have the necessary effect. We believe all petitions should be published either prior to, or at the time of, submission.

Finally, in light of current aggressive efforts of regulated industries to use uniform

standards as a means of preempting state tort liability,[2] it is important that the Agency say clearly what its intent and expectation is in this regard. The Agency states:

> States and local jurisdictions are preempted by the FMIA and PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA.

[29230] So long as the Agency intends this, consistent with the Supreme Court's recent reasoning in *Bates v. Dow Agrosciences*, to apply solely to labeling requirements, then its statement on preemption is consistent with the stated intent of the proposed rule to ensure that "food labels are truthful and not misleading." But to the extent that its statement is ambiguous or open-ended enough to support an argument in favor of total preemption of all state laws affecting federally-inspected products, then the statement should be revised, and made more specific and precise. As the USDA's own research has demonstrated, the ability to sue for product-related injuries are an important economic incentive for making food products safer, and further industry food-safety innovation.[3]

We hope that that the foregoing comments are of use to the Agency, and we thank it for the opportunity to participate in Agency consideration of this proposed rule. As we stated at the outset, we believe that adoption of the proposed rule is unnecessary if it will not result in the comprehensive review of food standards that the Agency thinks is needed for purposes of modernization. The Agency should seek the resources necessary to meet this goal itself, without outsourcing it to external parties. Finally, if the proposed rule is adopted, we believe that it is crucially important that the Agency speak clearly about the scope of preemption it expects or intends. Failing to do so could put the public seriously at risk of injury by products that may not be deemed to contain a defect for purposes of a label, but that may, depending on the circumstances, still be otherwise dangerous.

Very truly yours,

Denis W. Stearns

cc: File

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[2] *See, e.g. Bates v. Dow Agrosciences*, 544 U.S. ___ 2005) (holding that FIFRA labeling requirements preempted contrary state law regulations, but not state law tort claims for damages caused by the defective nature of the product); *Kriefall et al. v. Excel Corp.*, 265 Wis. 2d 476 (Wis. App. 2003) (holding that the FMIA adulteration standards do not preempt state law tort claims). Consider also the National Uniformity for Food Act promoted by the Grocery Manufacturers of America ("GMA"), which would require national uniformity for product warnings associated with labeling, advertising or other forms of public communication by the regulated industry that could then provide the basis for federal preemption like that used successfully for decades by the tobacco industry.

[3] *See* Jean C. Buzby *et al.*, Product Liability and Microbial Foodborne Illness/AER-799 (Economic Research Service/USDA 2001).